



Movetis starts Phase III clinical trial with prucalopride in patients with opioid-induced constipation (OIC)

New trial marks first step in Movetis' label expansion strategy for Resolor[®]

Turnhout (Belgium) – 19 May 2010 (5:45 PM CET) – Movetis NV (MOVE), the European gastrointestinal (GI) speciality pharmaceutical company, announces today that it has started a Phase III clinical trial with prucalopride in patients with constipation induced by opioid based pain medications. Positive results from its OIC clinical trial programme should allow Movetis to support a regulatory application for expansion of the current label of Resolor[®] (prucalopride)¹, so that physicians could have access to a new and innovative oral medication for the treatment of OIC.

As the OIC market is segmented into cancer and non cancer-related OIC, the prucalopride Phase III programme for this potential new indication consists of two trials. The Phase III clinical trial with prucalopride in non cancer-related OIC patients has now started as the screening of the first patients has begun. This twelve-week randomised, double-blind, placebo-controlled trial will involve over 500 patients from centres in ten European countries. The Phase III trial in cancer-related OIC patients is expected to be initiated within the year, which should enable Movetis to finalise the OIC clinical study reports late 2012 - early 2013.

Prior to the Phase III programme, prucalopride was tested for treatment of OIC in a Phase II placebo-controlled study including 190 patients. In this study, prucalopride demonstrated an effect on bowel frequency and symptoms related to OIC. The study did not provide an indication for interaction with the opioid analgesic effect. 67.2% of patients in the 2mg prucalopride group had three or more spontaneous bowel movements (SBM) after one week of treatment, versus 46.9% in the placebo-group. For the more stringent criterion of spontaneous *complete* bowel movements (SCBM), response rates after one week of treatment were 25.0% for patients in the 2mg prucalopride group compared to 3.1% in the placebo group. Similar results were obtained over 4 weeks of treatment. These Phase II study findings support that there is a role for the drug in treating OIC, which will now be studied in Phase III studies involving larger patient groups.

¹ Resolor (prucalopride) currently approved in thirty European countries (EU27, Norway, Iceland and Liechtenstein) for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief

In Europe, it is estimated that there are 2 million patients (of whom 40-50 % are cancer patients) receiving opioids for moderate-to-severe pain who experience severe constipation². This compares to the estimated 6 million patients³ that Movetis is currently targeting with its initial indication for Resolor¹.

Dirk Reyn, CEO of Movetis commented: "We continue to advance the development of Resolor, as scheduled. The OIC clinical trial programme that we initiated today is the first step in a well-thought out label expansion strategy, that is designed to eventually double the current patient population suffering from disorders which may be treated by prucalopride . In addition to prucalopride's initial indication and OIC, Movetis also plans to undertake clinical studies with prucalopride this year for a number of other potential additional indications including chronic constipation in males and paediatric constipation"

Note to editors:

About OIC - An unmet medical need in severely ill patients

Opioid based pain medications such as morphine, fentanyl, hydromorphone and oxycodone are used by healthcare practitioners to control moderate to severe pain in a variety of diseases and conditions. Opioids relieve pain by interacting with specific receptors that are located in the brain and spinal cord. At the same time, opioids also activate receptors in the gut which may result in constipation with formation of dry hard stools, delayed gastric emptying, abdominal cramping, bloating, nausea and vomiting. OIC has a serious negative impact on quality of life and the daily activities patients feel able to perform. Severe constipation may limit opioid therapy and therefore analgesia, which significantly impairs quality of life further⁴. Recently developed drugs such as methylnaltrexone offer a rescue treatment for severe OIC (not indicated for chronic use) and are currently only available as a subcutaneous formulation. Movetis believes that there is a need for an effective oral drug for more chronic usage with a convenient once a day dosing schedule and that is devoid of any impact on central or local opioid receptors.

² Estimate, based on IMS data and epidemiologic data

³ Estimate of female patients with chronic constipation who have sought medical advice and who are dissatisfied with traditional treatment options (based on IMS data and epidemiologic data)

⁴ Thomas JR, et al. *J Palliat Med* 2008; 11: S1-19.

About Movetis

Movetis is a European specialty GI company that is focused on improving the lives of millions of patients – both adults and children – by discovering, developing and commercialising innovative treatments targeting GI conditions with a high unmet medical need. Movetis NV was founded in Belgium in November 2006 as a spin-off of Johnson & Johnson.

Movetis has a broad portfolio of GI products: Resolor® (prucalopride) is approved in the European Economic Area for the indication “symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief”. The marketing authorisation application is currently under review in Switzerland. Two products are in Phase II development and Movetis has two prioritised compounds in preclinical development, all addressing important GI areas including ascites, paediatric reflux, refractory GORD (gastroesophageal reflux disease) and severe forms of irritable bowel syndrome. In addition, Movetis has rights to a large library of qualified lead compounds with potential for development in different GI indications and access to know how for compounds in secretory diarrhoea. The current portfolio is licensed from Janssen Pharmaceutica NV, Belgium and Ortho-McNeil Pharmaceutical Inc., two Johnson & Johnson companies.

Movetis shares are listed on Euronext Brussels under the ticker MOVE.

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